

DAG 4/26

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

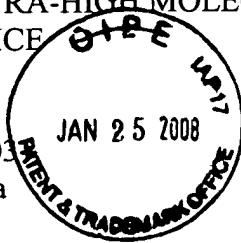
Applicant: Daniel J. Cooke et al.

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN AN ELECTRICAL MEDICAL DEVICE

Docket No.: 279.445US1

Filed: September 12, 2003

Examiner: Joseph A. Stoklosa



Serial No.: 10/662,129

Due Date: N/A

Group Art Unit: 3762

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- Return postcard.
- Petition To Withdraw Holding of Abandonment Under 37 CFR 1.181 (2 pgs.).
- Copy of Returned Stamped Postcard (1 pg.).
- Copy of Originally Filed Transmittal (1 pg.).
- Copy of Originally Filed Extension of Time (1 pg.).
- Copy of Originally Filed Amendment and Response Under 37 CFR § 1.111 (12 pgs.).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

Customer Number 21186

By: 
Atty: Zhengnian Tang
Reg. No. 55,666

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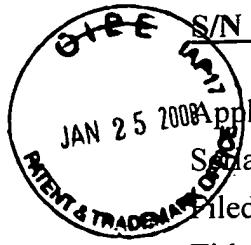
Chris Solis

Name

Chris Solis
Signature

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

(GENERAL)



S/N 10/662,129

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Daniel J. Cooke et al. Examiner: Joseph Stoklosa
Serial No.: 10/662,129 Group Art Unit: 3762
Filed: September 12, 2003 Docket: 279.445US1
Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN
AN ELECTRICAL MEDICAL DEVICE

PETITION TO WITHDRAW HOLDING OF ABANDONMENT
UNDER 37 CFR 1.181

Commissioner for Patents
MS: Petition
P.O. Box 1450
Alexandria, VA 22313-1450

A Notice of Abandonment dated December 28, 2007 for the above-identified patent application was received by our office on January 2, 2008. The Notice alleges that Applicant failed to timely file a proper reply to the Office Action dated June 4, 2007.

Applicant respectfully disagrees, since Applicant filed a response to the Office Action on December 4, 2007 with a Certificate of Mailing reflecting the same. In return, Applicant received a PTO-stamped postcard acknowledging receipt on December 10, 2007 of the submitted Response by the USPTO. The USPTO has the date filed as December 10, 2007 when it should state that this was the date the documents were received and not filed. True and accurate copies of the documents mailed December 4, 2007 are enclosed. Therefore, Applicant has timely filed the response and respectfully requests reconsideration of the holding of abandonment.

It is believed that there is no action or omission by Applicant to support a holding that the above-identified application was or is abandoned. Accordingly, it is respectfully requested that the abandonment holding be withdrawn and prosecution resumed as soon as possible.

PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 CFR 1.181

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Serial Number: 10/662,129

Dkt: 279.445US1

Filing Date: September 12, 2003

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN AN ELECTRICAL MEDICAL DEVICE

Conclusion

It is Applicant's understanding that no fee is required for a petition to withdraw a holding of abandonment. (See MPEP 711.03(c)), and therefore no fee is enclosed. However, if a fee is required, please charge it to Deposit Account No. 19-0743.

Any questions concerning this submission may be directed to the Applicants' undersigned representative.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6965

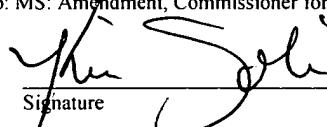
Date 1-21-2008

By 

Zhengnian Tang
Reg. No. 55,666

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Chris Sols
Name


Signature

COPY



Receipt is hereby acknowledged for the following in the United States Patent and Trademark Office:

In re Patent Application of: Daniel J. Cooke et al.

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN
AN ELECTRICAL MEDICAL DEVICE

Serial No.: 10/662,129

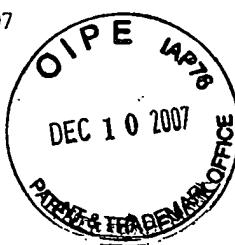
Filing Date: September 12, 2003

CONTENTS:

Amendment and Response (12 pgs.); Petition for Extension of Time (1 pg.); Authorization to charge Deposit Account 19-0743 in the amount of \$1050.00 to cover the Extension of Time Fee; return postcard and transmittal sheet

Mailed: December 4, 2007
ZT/klg

Docket No.: 279.445US1
Due Date: December 4, 2007



COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Daniel J. Cooke et al.

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN AN ELECTRICAL MEDICAL DEVICE

Docket No.: 279.445US1

Serial No.: 10/662,129

Filed: September 12, 2003

Due Date: December 4, 2007

Examiner: Joseph A. Stoklosa

Group Art Unit: 3762

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- Return postcard.
- Amendment and Response (12 pgs.).
- Petition for Extension of Time (1 pg.)
- Authorization to charge Deposit Account 19-0743 in the amount of \$1050.00 to cover the Extension of Time Fee.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

Customer Number 21186

By: 
Atty: Zhengnian Tang
Reg. No. 55,666

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Name

KATE GANNON

Signature

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

(GENERAL)



COPY

PATENT

S/N 10/662,129

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Daniel J. Cooke et al. Examiner: Joseph Stoklosa
Serial No.: 10/662,129 Group Art Unit: 3762
Filed: September 12, 2003 Docket No: 279.445US1
Title EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN
AN ELECTRICAL MEDICAL DEVICE

PETITION FOR A THREE-MONTH EXTENSION OF TIME

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

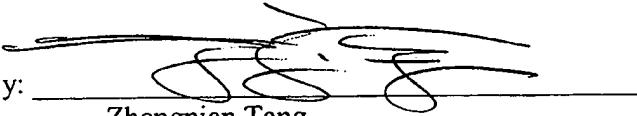
In accordance with the provision of 37 CFR § 1.136(a), it is respectfully requested that a three-month extension of time be granted in which to respond to the Office Action mailed June 4, 2007, said period of response being extended from September 4, 2007 to December 4, 2007.

Please charge Deposit Account No. 19-0743 in the amount of \$1050.00 to cover the required extension fee. Please charge any additional fees or credit overpayment to deposit Account No. 19-0743.

Respectfully Submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6965

Date: 12-4-2007

By: 

Zhengnian Tang
Reg. No: 55,666

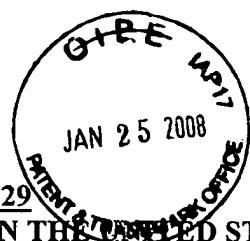
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Name: Mike Gauvin

Signature: Mike G

COPY

S/N 10/662,129



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Daniel J. Cooke et al.

Examiner: Joseph A. Stoklosa

Serial No.: 10/662,129

Group Art Unit: 3762

Filed: September 12, 2003

Docket No.: 279.445US1

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN
AN ELECTRICAL MEDICAL DEVICE

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This responds to the Office Action dated on June 4, 2007. Please amend the above-identified patent application as follows.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a three-month extension of the period for responding to the Office Action, thereby moving the deadline for response from September 4, 2007 to December 4, 2007.

IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) An electro-medical system comprising:
a container including an electrical device therein; and
a porous first covering over the container, wherein the porous first covering includes expanded-matrix ultra-high molecular weight polyethylene macromolecule that has an average molecular weight in a range from about 100,000 to about 5,000,000, and wherein the porous first covering includes a porous communication to the container.
2. (Canceled)
3. (Original) The electro-medical system of claim 1, the system further including:
a lead including a proximal end that is coupled to the container, a lead body, and a distal end including an electrode, wherein the electrode is covered with a porous second covering.
4. (Original) The electro-medical system of claim 1, wherein container is completely covered in the porous first covering.
5. (Original) The electro-medical system of claim 1, the system further including:
a lead including a proximal end that is coupled to the container, a lead body, and a distal end including a coil, wherein the coil is covered with a porous second covering.

6. (Original) The electro-medical system of claim 1, the system further including:

a lead including a proximal end that is coupled to the container, a lead body, and a distal end, wherein at least two of the proximal end, the lead body, and the distal end are covered with a porous second covering.

7. (Original) The electro-medical system of claim 1, the system further including:

a lead including a proximal end that is coupled to the container, and a distal end including an electrode, wherein the electrode is covered with a porous second covering; and

wherein at least one of the porous first covering and the porous second covering includes a pore structure that repels *in vivo* fibrotic tissue ingrowth.

8. (Original) The electro-medical system of claim 1, the system further including:

a lead including a proximal end that is coupled to the container, and a distal end including an electrode;
a dielectric coating over the proximal end; and
a porous second covering over the electrode.

9. (Original) The electro-medical system of claim 8, wherein the dielectric coating is selected from inorganics, silicone rubber, polyurethane, polytetrafluoro ethylene, fluoro polymers, and polyolefins.

10. (Original) The electro-medical system of claim 1, wherein the system further includes a plurality of leads.

11. (Currently Amended) The electro-medical system of claim 1, the system further including:

a lead including a proximal end that is coupled to the container, and a distal end including an electrode, wherein the electrode is covered with a porous second covering, and wherein the porous second covering is selected from the expanded-matrix ultra-high

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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molecular weight polyethylene, a porous fluoropolymer, a porous poly tetrafluoroethylene, a porous polyester, a porous polyurethane, a porous polyamide, and combinations thereof.

12. (Original) The electro-medical system of claim 1, wherein the container houses an electrical device, selected from a cardiac pacemaker, a cardiac defibrillator, a neurostimulator, and a combination thereof.

13. (Original) The electro-medical system of claim 1, wherein the container houses a monitor.

14. (Original) The electro-medical system of claim 1, wherein the container houses a monitor with a functionality selected from blood pressure, temperature, oxygen, at least one blood sugar, at least one lipoprotein, at least one blood gas, insulin, at least one electrolyte, heart rate, respiration, and a combination of at least two thereof.

15. (Original) The electro-medical system of claim 1, wherein the porous first covering over the container is disposed over a dielectric coating, and wherein the dielectric coating causes the container to be one selected from an insulated container and a hot can.

16. (Previously Presented) An electro-medical system comprising:
a lead including a lead proximal end, a lead body, and a distal end including electrical communication selected from an electrode, a wire, and a coil, wherein the porous covering includes an expanded-matrix ultra-high molecular weight polyethylene macromolecule that has an average molecular weight in a range from about 100,000 to about 5,000,000, wherein the lead includes a porous covering that includes a porous communication to the lead, and wherein the porous covering includes a pore structure that repels *in vivo* fibrotic tissue ingrowth.

17. (Canceled)

18. (Original) The electro-medical system of claim 16, the system further including:

a container that is coupled to the lead, wherein the container is covered with a porous first covering, and wherein the porous covering on the lead is a porous second covering.

19. (Original) The electro-medical system of claim 16, the system further including:

a dielectric coating over at least one of the proximal end and the lead body.

20. (Original) The electro-medical system of claim 19, wherein the dielectric coating is selected from inorganics, silicone rubber, polyurethane, polytetrafluoro ethylene, fluoro polymers, and polyolefins.

21. (Original) The electro-medical system of claim 16, wherein the lead is one of a plurality of leads.

22. (Previously Presented) An electro-medical system, comprising:

a container including an electrical device;
a dielectric coating over the container;
a passage through the dielectric coating to form an exposed portion of the container; and
a porous first covering over the exposed portion of the container, wherein the porous first covering includes an expanded-matrix ultra-high molecular weight polyethylene macromolecule that has an average molecular weight in a range from about 100,000 to about 5,000,000.

23. (Canceled)

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24. (Original) The electro-medical system of claim 22, the system further including:

 a lead including a proximal end that is coupled to the container, a lead body, and a distal end including an electrode, wherein the electrode is covered with a porous second covering.

25. (Original) The electro-medical system of claim 22, the system further including:

 a lead including a proximal end that is coupled to the container, a lead body, and a distal end including an electrode, wherein at least two of the proximal end, the lead body, the distal end, and the electrode are covered with a porous second covering.

26. (Original) The electro-medical system of claim 22, the system further including:

 a lead including a proximal end that is coupled to the container, and a distal end including an electrode, wherein the electrode is covered with a porous second covering; and

 wherein at least one of the porous first covering and the porous second covering has a pore structure that repels *in vivo* fibrotic tissue ingrowth.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Serial Number: 10/662,129

Dkt: 279.445US1

Filing Date: September 12, 2003

Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN AN ELECTRICAL MEDICAL DEVICE

REMARKS

This responds to the Office Action mailed on June 4, 2007.

Claims 1 and 11 are currently amended. Claims 1, 3-16, 18-22 and 24-26 remain pending in this application.

§102 Rejection of the Claims

Claims 1, 4, 16 and 19-21 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Bush (U.S. Patent No. 5,755,762, herein “Bush”).

Claims 1 and 16

Claims 1 and 11 have been amended to correct typographic errors.

Applicant respectfully traverses the rejection of claims 1 and 16 and submits that the Office Action does not set forth a proper *prima facie* case of anticipation or obviousness because Bush does not provide the claimed subject matter. For example, Applicant is unable to find in Bush, among other things, a teaching or suggestion of expanded-matrix ultra-high molecular weight polyethylene macromolecule (eUHMWPE) that has an average molecular weight in a range from about 100,000 to about 5,000,000, as recited in independent claims 1 and 16.

The Office Action states, in paragraph 6:

Bush discloses that the porous tubular covering may be made of various materials, including polyethylene (see col. 6, lines 1-13, especially line 5). Examiner considers this polyethylene to be the claimed “expanded ultra-high molecular weight polyethylene macromolecule” since the material of Bush is characterized by pore sizes suitable to allow penetration of bodily fluids but small enough such that fibrous tissue ingrowth is reduced (see col. 6, lines 13-22).

This assertion is respectfully traversed. Bush states, in portions cited in the Office Action (col. 6, lines 1-9):

Porous tubular covering 10 may be made of a fluoropolymer, polyester, polyurethane, cellulose acetate, mixed esters of cellulose, acrylic copolymer on nylon support, polyvinyl difluoride, polysulfone, polypropylene, cellulose nitrate, polycarbonate, nylon, and polyethylene. Preferably, the covering material is a fluoropolymer such as PTFE, FEP, or PFA, and most preferably, PTFE. Covering 10 may be a composite of two or more materials, such as a laminate of acrylic copolymer on a nylon support.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Because polyethylene is not described as a preferred material, and the covering 10 “may be a composite of two or more materials”, the cited portions of Bush do not provide that polyethylene is necessarily a material having the characteristics as alleged in the Office Action. Additionally, the Examiner does not set forth a reason how the alleged pore sizes of Bush’s material lead to the conclusion that its polyethylene is eUHMWPE. Therefore, it is believed that Bush does not provide the eUHMWPE as recited in claims 1 and 16.

Regarding the molecular weight, as recited in claims 1 and 16, the Office Action states, in paragraph 7:

Examiner interprets the polyethylene to inherently have an average molecular weight of 100,000 to 5,000,000 since polyethylene, such as linear low density polyethylene has a molecular weight in the 105 range and UHMWPE in the 106 range ...

This statement is respectfully traversed as an improper and unsupported assertion of inherency. Applicant is unable to find in Bush any teaching or suggestion that the polyethylene is a liner low density polyethylene or UHMWPE, and the Office Action does not provide any extrinsic evidence showing that polyethylene as disclosed in Bush must be such a polyethylene. Applicant respectfully requests a clarification on how the teachings of Bush and/or extrinsic evidence support the assertion of inherency, or withdrawal of the assertion of inherency.

The Office Action further states, in paragraph 8:

In the alternative, it would have been obvious for one or [sic] ordinary skill in the art at the time the invention was made to modify the system with UHMWPE with average molecular weight from 100,000 – 5,000,000 since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

This statement is respectfully traversed as a form of improper use of official notice. It is believed that choosing the eUHMWPE is not merely “discovering the optimum value”. It is also believed that choosing molecular weight relates to choosing a type of material rather than merely “discovering the optimum value” of the material. Thus, pursuant to M.P.E.P. § 2144.03, Applicant respectfully requests a reference or an affidavit of personal knowledge by the Examiner showing that choosing the eUHMWPE having an average molecular weight in a range from about 100,000 to about 5,000,000 is merely a matter of “discovering the optimum value”, or withdrawal of the obviousness rejection.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Additionally, by stating “[p]referably, the covering material is a fluoropolymer such as PTFE, FEP, or PFA, and most preferably, PTFE” (col. 6, lines 6-7), Bush in fact teaches away from actually using polyethylene as its covering material.

Applicant respectfully requests reconsideration and allowance of claims 1 and 16.

Claims 4 and 19-21

Claim 4 is dependent on claim 1. Claims 19-21 are dependent on claim 16. Claims 1 and 16 are believed to be patentable for at least the reasons set forth above. Therefore, the discussion above for claims 1 and 16 are incorporated herein to support the patentability of claims 4 and 19-21.

Applicant respectfully requests reconsideration and allowance of claims 4, and 19-21.

§103 Rejection of the Claims Using Soukup and Bush

Claims 1, 3-14, 16 and 18-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soukup et al. (U.S. Patent No. 6,704,604, herein “Soukup”) in view of Bush.

Claims 1 and 16

Claims 1 and 11 have been amended to correct typographic errors.

Applicant respectfully traverses the rejection of claims 1 and 16 and submits that the Office Action does not set forth a proper *prima facie* case of obviousness because Soukup and Bush, individually or in combination, do not provide the claimed subject matter. For example, Applicant is unable to find in Soukup and Bush, individually or in combination, among other things, expanded-matrix ultra-high molecular weight polyethylene macromolecule (eUHMWPE) that has an average molecular weight in a range from about 100,000 to about 5,000,000, as recited in independent claims 1 and 16.

The rejection relies on Bush to provide the eUHMWPE as recited in claims 1 and 16. Therefore, the discussion above supporting the patentability of claims 1 and 16 over Bush is incorporated herein. As discussed above, it is believed that Bush does not provide the claimed eUHMWPE that has an average molecular weight in a range from about 100,000 to about 5,000,000.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Additionally, by stating that PTFE is the most preferable covering material, Bush teaches away from the proposed modification of Soukup's covering with Bush's polyethylene. The Office Action states, in paragraph 14, that "Soukup et al. discloses that the porous covering is constructed from porous PTFE, and thus fails to teach that the porous covering may include 'expanded ultra-high molecular weight polyethylene macromolecule.'" However, Bush states (col. 6, lines 6-7): "Preferably, the covering material is a fluoropolymer such as PTFE, FEP, or PFA, and most preferably, PTFE." Because Soukup uses PTFE, the most preferable material according to Bush, for the covering, Bush in fact teaches away from using another material and hence the proposed combination of references.

Applicant respectfully requests reconsideration and allowance of claims 1 and 16.

Claims 3-14 and 18-21

Claims 3-14 are dependent on claim 1. Claims 18-21 are dependent on claim 16. Claims 1 and 16 are believed to be patentable for at least the reasons set forth above. Therefore, the discussion above for claims 1 and 16 are incorporated herein to support the patentability of claims 3-14 and 18-21.

Applicant respectfully requests reconsideration and allowance of claims 3-14 and 18-21.

§103 Rejection of the Claims Using Soukup, Bush, and Czura

Claims 15, 22 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soukup et al. in view of Bush as applied above, and further in view of Czura et al. (U.S. Patent No. 5,562,715, herein "Czura").

Claim 15

Claim 15 is dependent on claim 1, which believed to be patentable for at least the reasons set forth above. It is believed that the addition of Czura does not remedy the deficiency of Soukup and Bush as discussed above for claim 1. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claim 15.

Applicant respectfully requests reconsideration and allowance of claim 15.

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Title: EXPANDED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE IN AN ELECTRICAL MEDICAL DEVICE

Claim 22

Applicant respectfully traverses the rejection of claim 22 and submits that the Office Action does not set forth a proper *prima facie* case of obviousness because Soukup, Bush, and Czura, individually or in combination, do not provide the claimed subject matter. For example, Applicant is unable to find in Soukup, Bush, and Czura, individually or in combination, among other things, expanded-matrix ultra-high molecular weight polyethylene macromolecule (eUHMWPE) that has an average molecular weight in a range from about 100,000 to about 5,000,000, as recited in independent claim 22.

Because the rejection applies the proposed combination of Soukup and Bush, the discussion above supporting the patentability of claims 1 and 16 over Soukup and Bush are incorporated herein to support the patentability of claim 22. In summary, as discussed above, it is believed that Bush does not provide the claimed eUHMWPE that has an average molecular weight in a range from about 100,000 to about 5,000,000, and in fact teaches away from the proposed modification of Soukup's covering with polyethylene. It is believed that the addition of Czura does not remedy the deficiency of Soukup and Bush as discussed above for claims 1 and 16.

Applicant respectfully requests reconsideration and allowance of claim 22.

Claims 24-26

Claims 24-26 are dependent on claim 22, which is believed to be patentable for at least the reasons set forth above. Therefore, the discussion above for claim 22 is incorporated herein to support the patentability of claims 24-26.

Applicant respectfully requests reconsideration and allowance of claims 24-26.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6965 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6965

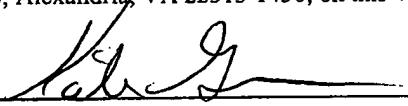
Date 12-4-2007

By


Zhengnian Tang
Reg. No: 55,666

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ATE GANSON
Name


Signature